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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,874	09/05/2001	Johann Michael Koehler	F-7129	6041

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EXAMINER

NAGPAUL, JYOTI

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,874	Applicant(s) KOEHLER, JOHANN MICHAEL	
	Examiner Jyoti Nagpaul	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/15/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. The drawings are objected to because in Figure 1, it is highly unclear to examiner whether the passage openings and channel are extending from the surface of the substrate or formed in the substrate. In regards to Figure 1, the drawing does not clearly suggest the channel is longitudinally extended through the entire substrate. It is highly unclear and indefinite to what the applicant is claiming. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 1-15** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to "*passage openings are separated from the channel by a partially permeable sieve-like membrane*" in Lines 7 and 8 of Claim 1, it is unclear as to where the membrane is. Is applicant claiming the passage openings on the **second** substrate wafer is separated from the channel on the **first** substrate by a membrane as shown in Figure 1? It is unclear whether applicant is claiming the embodiment of the second substrate of Figure 1 or Figure 2.

In regards to "*said passage*" in Line 14 of Claim 1. It is unclear and indefinite what passage is the applicant claiming.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Luft.

Luft discloses a instrument that includes a first substrate (30) and a second substrate (31) wafer being engaged to one another in a common plane, where a

longitudinally extending channel (41) is inserted into one substrate (30) wafer, The channel (41) is captured by two passage openings (42, 40), which are passed through the substrate wafer. Filter elements (35, 34) are provided, and the passage openings are separated from the channel by a partially permeable sieve-like membrane (34, 35). The membrane has transmission areas (43, 40) so that they prevent micro-beads and/or cells, which are introduced into the channel (41), from entering into the passage openings. The channel is provided with two further openings outside (40, 42) of the section captured by passage openings. The two openings (40, 42) are adapted to enable a loading and/or a displacement of the micro-beads and/or cells, provided above the section captured by a passage, by applying a fluidic pressure and further comprising means for temporarily closing at least one of the passage openings and one of the further openings. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. **Claims 1 and 9-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang, Wang, Locascio and Lee (Herein Jiang).

Jiang discloses a microfluidic device that includes a first substrate (I, see Figure 1) and a second substrate (III) wafer being engaged to one another in a common plane,

where a longitudinally extending channel (see figure 3) is inserted into one substrate wafer, The channel is captured by two passage openings (see Figure 1 or 3), which are passed through the substrate wafer. Filter elements (PVDF membrane, see Figure 1 or 3) are provided, and the passage openings are separated from the channel by a partially permeable sieve-like membrane. The membrane has transmission areas (see Figure 3) so that they prevent micro-beads and/or cells, which are introduced into the channel, from entering into the passage openings. The channel is provided with two further openings outside (see Figure 3) of the section captured by passage openings. The two openings is adapted to enable a loading and/or a displacement of the micro-beads and/or cells, provided above the section captured by a passage, by applying a fluidic pressure and further comprising means for temporarily closing at least one of the passage openings and one of the further openings. (Also refer to Figure below) Jiang discloses plurality of substrate wafers that include two passage openings each and linearly fluidically interconnected by channels. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

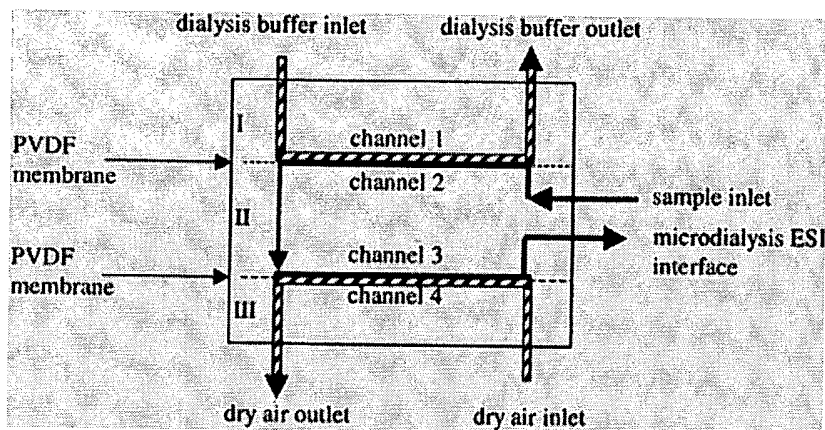


Figure 1. Jiang Microfluidic Device

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 2 and 5-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Luft or Jiang (in the alternative) in view of Saaski.

In regards to **Claim 2**, Jiang and Luft fail to disclose the first substrate wafer is made of glass and the second substrate is made of silicon.

In regards to **Claim 5**, Jiang and Luft fail to disclose anodic bonding bonds the two substrates.

In regards to **Claim 6 and 7**, Jiang and Luft fail to disclose the first and second substrate are connected by adhesive means.

Saaski discloses a fluid handling device where one substrate is made of glass and the second substrate is made of silicon and where they are bonded by anodic bonding. (See Column 29, Lines 1-3). Saaski further discloses other means for bonding the two substrates such as adhesive, glue, epoxy, glass solder and metal solder. (See Column 39, Lines 11-18)

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a glass substrate and a silicon wafer bonded

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by different means as disclosed in Saaski because it is inexpensive and cost effective in order to more efficiently separate complex substance mixtures.

In regards to **Claim 8**, Jiang and Luft fail to disclose an additional channel that extends to the rim of the substrate.

Saaski discloses a substrate with two passage openings extending to the rim of the substrate. (Refer to Figure 7)

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include an additional channel of which extends to the rim of the substrate of Saaski in order to increase the transmission area, thus, making the process more efficient and cost effective.

11. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Luft or Jiang (in the alternative) in view of Quake.

Jiang and Luft fail to disclose the first substrate wafer is made of glass and the second substrate wafer is made of synthetic material.

Quake discloses a microfluidic device where one substrate is made of silicon elastomer and the second substrate is glass. (See paragraph [0088], pg 10)

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a glass substrate and a synthetic material substrate in Quake because it is inexpensive and cost effective to use synthetic materials in order to efficiently carry out the process.

12. **Claims 13 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang in view of Bonne.

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Jiang fails to disclose two channel sections in the shape of two truncated pyramids.

Bonne discloses a microfluidic device that contains a channel in the shape of a truncated pyramid. (Refer to Figure 10)

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a truncated pyramid channels of which extends to the rim of the substrate of Bonne in order to avoid any undue pressure drop for fluid flowing through the microfluidic device.

Allowable Subject Matter

13. Claims 4 and 15 are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Prior art does not disclose or fairly suggest a perforated polymeric foil membrane and nano-porous thin-layer membrane where the pore sizes range of 5 to 500nm.

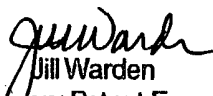
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN


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